Fournitures Hospitalieres Industrie
Patricia Donnard
Regulatory Affairs Manager
ZI de Kernevez - 6 rue Nobel
Quimper 29000
FRANCE

January 23, 2018

Re: K171789
Trade/Device Name: ARROW® Reverse Porous Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: December 14, 2017
Received: December 18, 2017

Dear Patricia Donnard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement on last page*

510(k) Number *(if known)*
K171789

Device Name

ARROW® Reverse porous glenoid

Indications for Use *(Describe)*

REVERSE PROSTHESIS (METAL-BACK OR POROUS GLENOID IMPLANT)
The ARROW Reverse Shoulder Prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the glenoid baseplate (metal-back or porous) is intended for cementless application with the addition of bone screws for fixation.

Type of Use *(Select one or both, as applicable)*	
☒Prescription Use (Part 21 CFR 801 Subpart D)	☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of 21 CFR 807.92.

Date: January 17, 2018

The assigned 510(k) number is: K171789

Applicant

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Product

Trade name: ARROW® Reverse porous glenoid

Common name: Shoulder prosthesis

Classification: Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Product code: PHX, KWS, KWT
Regulation number: 21 CFR 888.3660
Class: II

Information on predicate devices to which substantial equivalence is claimed

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	ARROW Reverse Shoulder System
510(k):	K112193
Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	ARROW Reverse Shoulder long keel and short keel glenoid base
510(k):	K142778
Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	ARROW Anatomical porous glenoid base
510(k):	K162068

Manufacturer:	TORNIER SAS
Device Trade Name:	AEQUALIS Reversed Shoulder Prosthesis
510(k):	K132285

Manufacturer:	Zimmer
Device Trade Name:	TRABECULAR metal, Reverse Shoulder System
510(k):	K052906

Reference Devices:

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	ARROW Anatomical porous glenoid base
510(k):	K162068

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	CoLS Fixation System
510(k):	K120740

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	CALCANAIL
510(k):	K150463 and K150471

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	ARROW Anatomic shoulder system
510(k):	K093599

Device description

The ARROW® Reverse porous glenoid base is used in total reverse shoulder prosthesis and is designed to articulate with the ARROW® Reverse shoulder system (cleared in K112193). The porous glenoid base is used with bone screws for fixation (cleared in K112193).

The ARROW® Reverse porous glenoid is intended to be implanted using the dedicated instrumentation supplied by the manufacturer. This instrument set is common for all the configurations of prosthesis: simple humeral prosthesis, total anatomical prosthesis and reverse prosthesis.

Indications for use / Intended use

- Indications for use

REVERSE PROSTHESIS (METAL-BACK OR POROUS GLENOID IMPLANT)
The ARROW Reverse Shoulder Prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the glenoid baseplate (metal-back or porous) is intended for cementless application with the addition of bone screws for fixation.

- Intended use

All the implants of shoulder prosthesis are used for primary or revision surgeries.
The glenoid bases (metal-back or porous) are intended for cementless application with the addition of cortical or cancellous bone screws. The porous glenoid base must be used for a total anatomical or reverse prosthesis.

Comparison of technological characteristics

The ARROW Reverse porous glenoid and the above selected predicate devices have the same intended use and substantial similar indications for use and share the following similarities:

- they are made out of the same material (titanium alloy),
- they are available in similar ranges of sizes,
- they bear design features similarities.

Performances

The ARROW Reverse porous glenoid was tested according to the standards ASTM F1829-16, ASTM F2028-14 and ASTM F1378-12. After the tests were completed, it was determined that the ARROW Reverse porous glenoid performances were substantially equivalent to those of the selected predicate devices.

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

The LAL testing meets the specified 20EU/device limit.

Substantial equivalence

The substantial equivalence of our products, when compared to the selected predicate devices, has been established following the commercial documents, 510(k) submission's information as well as conformance to standards in force.
The analysis of these technical data allows us to submit the ARROW Reverse porous glenoid, as being substantially equivalent to the already cleared predicate devices selected to draw a comparison.

Conclusion

Following the examination of all the above mentioned information, we believe that the ARROW Reverse porous glenoid is substantially equivalent to the selected predicate devices in terms of intended use, ranges of sizes, materials, performances, safety and effectiveness.